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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Christoph Kirsch

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1633

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/831,272	Applicant(s) KIRSCH ET AL.	
	Examiner MARIA B. MARVICH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,8,9,22,39,42-47 and 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,9,39,44-46 and 51-59 is/are rejected.
- 7) ☒ Claim(s) 2,3,5,39,42,46,47,49,55 and 58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/5/10 has been entered. Claims 2, 3, 8, 9, 22, 39, 42-47, 49 and 50-58 are pending and under examination.

Receipt of an updated and corrected Application Data Sheet filed 12/3/09 is acknowledged.

It is noted that the amendment has been improperly submitted. Specifically, the claims filed 12/3/09 should not be the source of the most recent amendments noted 1/5/10 as the 12/3/09 amendments were not entered. In the interest of expediting prosecution, the amendment has been considered as is.

Claim Objections

Claims 2, 3, 39, 42, 46, 47, 49, 50-52, 55 and 58 are objected to because of the following informalities: in each of claims 2, 3, 42, 47, 49, 50 and 51 should be amended to recite in line 3 - wherein the chimeric promoter comprises--. There are two promoters referenced through a number of the claims- a minimal promoter and a chimeric promoter. Recitation of "the promoter" does not indicate adequately to which the claims refer. Claims 3 and 49 refer to a chimeric promoter comprising (i) two or more cis-elements and (ii) a minimal promoter. The

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claims also recite “further comprising” which is in reference to the chimeric promoter. For consistency and clarity, it would be preferable to recite (iii) a cis-acting element having the nucleotide sequence-- as this element is part of the promoter.

Claim 39, upon consideration, requires several amendments. First, the preamble should, as recommended in the advisory mailed 12/15/09 indicate that the promoter is the chimeric promoter. As well, the promoter is not obtained by a method of rendering a gene responsive to pathogens but is designed to perform such a function. --A chimeric promoter to render a gene responsive to pathogens, obtained by a method comprising --. Secondly, each of (1) and (2) should be amended to recite for consistency, for example, --(1) the at least one cis-acting element mediates induction of local gene expression in plants upon the pathogen elicitor treatment, the pathogen infection, or both to between--.

For simplicity, claim 42 (i) should be amended to recite in line 6, --wherein the two or more cis-acting elements--.

Claims 46, 55 and 58 recite “introducing a chimeric promoter” into the plants whereas when referring to previously recited limitations it is proper to use the article “the” as opposed to “a”. In this case the claim should be amended to --the chimeric promoter--. As well, the recitation “and/or” in the last sentence is inconsistent with the recitation of only “or” in the preamble.

Appropriate correction is required.

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Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 9, 39, 44-46, 51 and 53-59 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment. The dependent claims are include in the rejection as they do not obviate the rejection.**

Claim 39 (4) and claim 51 are drawn to synthetic promoters comprising two or more cis-acting elements sufficient to direct the pathogen induced expression. The amendment to claim 39 and new claim 51 has added that this synthetic chimeric promoter is further linked to a cis element having the nucleotide sequence selected from SEQ ID NO:s 5, 6, 8, 9, 10, 12 and 13. The specification teaches that these sequences are 5= W3, 6 = W_{amy}, 8 and 9= N, 12 and 13= U and 10 is unclear as to what sequence it corresponds. Discussion of chimeric promoters is indicated as presented in Example 5. Example 5 does not demonstrate W3, W_{amy}, N or U in linkage with D. The text discusses quite generically that "All elements (Boxes W1, W2, S, U, D, N and W_{Amy}) are active in combination with each other; monomer, dimer and tetramer constructs being active." However, the claim actually requires formation of a chimeric promoter that is then in further linkage with one of these elements. This requires a combination that is not disclosed in the specification. "It is not sufficient for purposes of the written description

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requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.” *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997). Each of these multiple chimeric promoters represents unique structures that are not so disclosed or described in the specification. Therefore, the fragments are unnamed species and the specification does not support inclusion of this species in the recited invention. The MPEP teaches, “New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). (see e.g. MPEP 2105).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 39, 44-46, 52 and 56-59 are rejected under 35 U.S.C. 102(b) as being anticipated by van de Locht et al (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document).

This is a new rejection necessitated by applicants’ amendment by addition of new claim 51

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and to amendment to claim 39 wherein both recite a chimeric promoter comprising SEQ ID NO:1 (part 5 of claim 39).

Van de Locht et al teach a promoter obtainable by insertion of pPR2-10, which comprises at least one cis-acting element sufficient to direct elicitor-specific expression into the promoter of the GUS reporter gene as recited in claim 39. pPR2-10 comprises SEQ ID NO:11 as indicated in figure 5 which demonstrates that pPR2-10 comprises the region from -168 to -43. This region comprises SEQ ID NO: 11 and functions as a cis-element sufficient to direct elicitor specific expression with the CAAT element. Hence the vector comprises at least two-cis acting elements wherein the sequences of SEQ ID NO:11 and CAAT are separated by at least 50 bases.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 39, 44-46, 52 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van de Locht et al (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document) in view of Pears and Williams (Nucleic Acids Research, 1988, Vol 16(17), pages 8467-84861; see entire document) and Searle et al, MCB, 1985, Vol 5(6), pages 1480-1489; see entire document) further in view of Comai et al (Plant Molecular Biology, 1990, Vol 15(3), pages 373-381; see entire document). **This is a new rejection necessitated by applicants'**

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amendment by addition of new claim 51 and to amendment to claim 39 wherein both recite a chimeric promoter comprising SEQ ID NO:1 (part 5 of claim 39).

Applicants claim a chimeric promoter comprising at least two elements sufficient to induce pathogen mediated expression wherein at least one is SEQ ID NO: 11.

Van de Locht et al teach a promoter obtainable by insertion of pPR2-10, which comprises at least one cis-acting element sufficient to direct elicitor-specific expression into the promoter of the GUS reporter gene. pPR2-10 comprises SEQ ID NO:11 (nucleotides -77 to -46) as indicated in figure 5, which demonstrates that pPR2-10 comprises the region from -168 to -43. This region comprises SEQ ID NO: 11 and functions as a cis-element sufficient to direct elicitor specific expression with the CAAT element. The promoter of van de Locht et al as disclosed in Figure 5 and 6 is a chimeric promoter formed by fusion of parsley chalcone synthase promoter (which provides the minimal promoter) to a PR2 fragment. Van de Locht et al do not teach that pPR2-10 comprises two copies of the elicitor element.

Pears and Williams teach that heterologous promoter sequences inserted into promoters can mediate sufficient gene expression (see e.g. abstract). Specifically, Pears and Williams teach that the promoter elements function "optimally" when multiple copies of the sequences are present (see e.g. page 8480 and figure 7).

Searle et al teach that promoters comprising two heterologous inducible elements isolated from the methallothionein I gene function as strong inducible promoter, whereas a single element did not respond to zinc (see e.g. abstract). Applicants reason that more than two should further increase the inducibility of the promoter.

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Comai et al teach that promoters can be duplicated with the effect of enhanced expression (see e.g. abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate the isolated promoter fragment that is elicitor responsive as taught by van de Locht et al as taught by Pears and Williams and Searle et al and Comai et al because and van de Locht et al teach that a fragment of the PR2 promoter is responsible for strong elicitor mediated gene activation and because Pears and Williams and Searle et al teach that multiple elements are more effective than single elements and Comai et al teach that it is within the ordinary skill of the art to generate chimeric vectors in which larger promoter elements are duplicated. One would have been motivated to do so in order to receive the expected benefit of enhanced regulation of heterologous genes. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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